Breath hold techniques for radiotherapy of esophageal carcinoma; a feasibility study.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Thoracic disorders (excl lung and pleura)
Study type	Observational invasive

Summary

ID

NL-OMON50465

Source
ToetsingOnline

Brief title
BROTHER study

Condition

- Thoracic disorders (excl lung and pleura)

Synonym
esophageal cancer, Esophageal carcinoma

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breath hold technique, Esophageal carcinoma, Radiotherapy

Outcome measures

Primary outcome

Part 1:

- Feasibility of 2 different DIBH methods

- Reproducibility of DIBH using 2 different methods on repeat CT

Part 2:

- Successfully delivered radiotherapy cycle using DIBH.

- Reproducibility of DIBH on daily cone beam CT (CBCT).

- Dose coverage of the clinical target volume (CTV) on weekly repeated CT*s.

Secondary outcome

nvt

Study description

Background summary

As survival improved after the introduction of the neo-adjuvant chemoradiotherapy (neo-CRT) in the curative treatment of esophageal cancer, it has become increasingly important to minimize radiation-induced toxicity in order to reduce the prevalence of long-term survivors suffering from long term and sometimes devastating side effects.
Radiation-induced pulmonary and cardiac toxicity are the most important late effects after radiotherapy for thoracic tumors, such as for esophageal cancer. Furthermore, pulmonary complications after esophageal resection can be enhanced by neo-CRT.
Our previous in-silico pilot study demonstrated the potential benefit of deep inspiration breath hold (DIBH) for radiotherapy of esophageal cancer. In the inspiration phase, the lungs extent substantially, up to two-fold, which enables a significant dose reduction to the heart (median 8 Gy) and lungs.
In this study, we aim to determine the clinical feasibility and reproducibility

of DIBH for photon radiotherapy of esophageal cancer with the aim to assure adequate dose coverage of the target while minimize the dose to the heart and/or the lungs.

Study objective

Part 1: The main objective of the first part of the study is to determine the most optimal method for DIBH (active breathing control vs voluntary coached) and its reproducibility. Based on these findings, one of these methods will be selected for part 2 of this study.
Part 2: The two main objectives of part 2 are: 1) To explore the feasibility of the use of DIBH, in clinical practice for the curative irradiation of esophageal cancer patients, using the method selected in part 1; i.e. are patients able to perform DIBH for the amount of times necessary for the irradiation of one full fraction, 2) To determine the reproducibility of this breath hold position during the entire RT treatment course and its consequences for the dose distribution.

Study design

Feasibility study (30 patients); part one: 10 patients, part two: 20 patients.

Study burden and risks

Participation in part 1 of this study involves the risk incurred by additional CT-scans. Patients will undergo a free breathing 4D planning-CT (including spiral CT), according to current standard, combined with 10 additional 3D CT*s in DIBH using 2 different methods.
In part 2 the patients included in this study will be treated with a new radiotherapy treatment technique. The main risks are under- or over dosage of the tumor and/or normal tissues, respectively. The risks are minimized by a pre-treatment robustness analyses on 3 DIBH CT scans and a daily online verification protocol using CBCT. Furthermore, weekly repeat CT*s are performed to monitor the dose coverage in more detail. If the dose coverage and distribution are insufficient, the patient will continue on its original treatment plan.
Part 2 of this study also involves the risk incurred by additional CT-scans. Patients will undergo a free breathing 4D planning-CT (including spiral CT), according to current standard, combined with 3 additional 3D CT*s in DIBH using the optimal method as defined in part 1. If patients are treated with DIBH full VMAT radiotherapy, the patient will undergo weekly repeated 3D CT*s (DIBH) and daily CBCT verification to monitor the inter-fraction variation and reproducibility of the breath hold and its dosimetric consequences for the treatment plan. Furthermore, the intra-fraction variation of the breath hold will be investigated with additional CBCTs after the treatment fraction twice a week.

If the DIBH treatment plan seems to be insufficient during the treatment course, an additional FB 4D CT will be performed to verify the usability of the FB partial VMAT treatment (standard of care) plan.

In total the study patient, that participates in the first part of the study will receive 10 extra CT scans, with an additional radiation dose of 10 x 10 mSv, which is relatively low, considering the radiation dose of the treatment itself (40-60 Gy).
Patients who participate in the second part will receive 8-9 extra CTs and 10-12 extra CBCTs. The additional radiation dose of these extra CT*s is again relatively low (8-9 x 10 mSv (DIBH) + 10-12 x 5 mSv (3D CBCT) when considered in relation to the radiation dose of the treatment itself (40-60 Gy).
Furthermore, the use of DIBH for the patients in part 2, might be beneficial to the patient since it will markedly reduce the radiation dose to the heart and/or lungs in a much larger extent than the additional radiation exposure resulting from the repeated imaging.
The additional dose of the FB 4D CT, which will be performed if the DIBH seems to be insufficient during the treatment course is 30mSv.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Histologically proven esophageal cancer of the mid or distal esophagus
• Scheduled for external-beam photon radiotherapy with curative intention
• WHO 0-2
• Age >= 18 years
• Written informed consent

Exclusion criteria

• Serious respiratory distress
• Contra-indication for fiducial marker placement
• Noncompliance with any of the inclusion criteria

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	10-01-2021
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	04-07-2018
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-01-2021
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL62619.042.17
Other	volgt